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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/737,403

12/16/2003

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EXAMINER

WOOLWINE, SAMUEL C

ART UNIT

PAPER NUMBER

1637

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/737,403	Applicant(s) WILLSON ET AL.	
	Examiner SAMUEL C. WOOLWINE	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-9, 11, 12 and 14-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-9, 11, 12 and 14-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/29/2009 and supplemental response of 11/27/2009 have been entered.

Claims 2-9, 11, 12 and 14-24 are pending in the application. All claims have been amended to depend directly or indirectly from claim 5.

The rejections over the prior art set forth in the Office action mailed 07/07/2009 are withdrawn since all claims depend from claim 5, which was indicated free of the art in that Office action. Any rejections not appearing below are considered no longer applicable. New rejections under 35 USC 112, 2nd paragraph are discussed below.

In addition, a formality issue with regard to nucleic acid sequences has been discovered, which is discussed following the rejections.

Specification

It is noted that paragraph [0059] of the published application states: "...in order to stabilize the aptamer in its stem-loop form (**FIG. 1**).\" This should actually refer to figure 2, not figure 1.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-9, 11, 12 and 14-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The preamble for claim 5 clearly recites "A scalable process for...the separation of a desired recombinant polymerase from undesired nucleic acid", but the body of the claim later recites "exposing purine bases present within either the desired nucleic acid product or undesired nucleic acid" and "capture of the desired nucleic acid product or undesired nucleic acid" (emphasis provided). There were previous claims during the prosecution of this application directed to purifying desired nucleic acids. However, claim 5 is a method for separating a desired recombinant polymerase from undesired nucleic acid. This problem was pointed out in the Office action mailed 07/07/2009 (paragraph spanning pages 23-24). In amending the remaining claims to depend from claim 5, certain limitations in the remaining claims, which only made sense for the embodiments of capturing a desired nucleic acid, should also have been amended to be consistent with claim 5. These issues are:

- (i) The inconsistency within claim 5 itself.
- (ii) In claim 4, referring to the captured nucleic acid as a "product".
- (iii) In claim 6, reference to "(or desired) nucleic acids".
- (iv) In claim 11, reference to "the desired supercoiled plasmid DNA product".

(v) In claim 12, reference to "supercoiled plasmid DNA product".

In addition to the issues indicated above, additional issues are:

Claim 2 recites "wherein the exposed purine base comprises a structural form selected from the group consisting of single stranded region of nucleic acid, Hairpins, Loops and modifications to the phosphate backbone". It is incorrect to say that a purine base could "comprise" these structural forms. For example, a purine base could not "comprise" a *region* of nucleic acid. It is recommended to phrase the limitation thusly: "wherein the expose purine base is found within a structural form selected from the group consisting of single stranded region of nucleic acid, hairpins, loops, or nucleic acid having modifications to the phosphate backbone."

Claim 6 recites "selected from the group consisting of", but then recites only one alternative: IMAC. It would be clearer to just that the separation step based on IMAC.

Claim 7 recites "comprising introducing single strandedness as an exposed purine base". This language is unclear. The following options would be more favorably considered: "A process according to claim 5, wherein exposing purine bases comprises introducing single strandedness." Or: "A process according to claim 5, comprising introducing single strandedness in the undesired nucleic acid."

Claims 11 and 12 are directed to embodiments for purifying a desired nucleic acid, not a desired polymerase.

Claims 23 and 24 recite the capture technique comprises HIC (hydrophobic interaction chromatography) and RPC (reversed phase chromatography). However,

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independent claim 5 recites the technique must be "selective" for exposed purine bases. According to paragraph [0025] of the published application (US 2006/0160093), whereas HIC and RPC are "selective for single stranded regions of nucleic acid", they are not disclosed as selective for exposed purine bases per se. Rather, this passage states: "We have shown that IMAC can selectively and efficiently capture nucleic acids containing exposed purine bases and separate them from the desired product." However, there is no indication that HIC or RPC are selective for exposed purine bases per se.

Sequence Compliance

This application discloses nucleic acid sequences falling within the definitions set forth in 37 CFR 1.821 through 1.825. Specifically, figure 2 and paragraphs [0056] and [0059] of the published application disclose such sequences. As noted in MPEP 2422.01, any unbranched nucleic acid sequence having 10 nucleotides or more, and specifying at least 4 nucleotides (i.e. nucleotides other than "n"), fall within these definitions. For this reason, the nucleotide sequence disclosed in paragraph [0060] of the published application is exempt from 37 CFR 1.821 through 1.825.

However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth below:

1. The application does not contain, as a separate part of the disclosure, a "Sequence Listing" as described in 37 CFR 1.821(c);
2. This application does not contain, a copy of the "Sequence Listing" in computer readable form as described in 37 CFR 1.821(e).

Applicant is required to provide the items in 1 and 2 above, an amendment specifically directing entry of the "Sequence Listing" into the application, and a statement that the "Sequence Listing" provided for each of items 1 and 2 are the same (37 CFR 1.821(f)) and introduces no new matter (37 CFR 1.821(g)). In lieu of separate copies of the "Sequence Listing" as specified in 37 CFR 1.821(c) and (e), Applicant may file the "Sequence Listing" electronically via EFS-Web (<http://www.uspto.gov/patents/ebs/index.jsp>), in which case the statement under 37 CFR 1.821(f) is not required. Note that the statement under 37 CFR 1.821(g) is still required, as is an amendment directing entry of the "Sequence Listing", even if filed via EFS-Web.

Finally, as set forth in MPEP 2421.03:

"Upon detection of damage or a deficiency, a notice will be sent to the applicant detailing the damage or deficiency and setting at least a 30-day period for reply. The period for reply will usually be 2 months when sent during the preexamination processing of an application. However, if the notice is sent out with an Office communication having a longer period for reply, the period for reply may be longer than 2 months, e.g., where the notice is sent with an Office action on the merits setting a 3-month period for reply. Extensions of time in which to reply will be available pursuant to 37 CFR 1.136."

Accordingly, the period for reply for compliance with the Sequence Rules will run concurrently with the period for reply to this Office action on the merits.

Alternatively, the specification may be amended to remove the sequences.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAMUEL C. WOOLWINE whose telephone number is (571)272-1144. The examiner can normally be reached on Mon-Fri 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Samuel Woolwine/
Examiner, AU 1637